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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,187	12/18/2001	Val Sheffield	IOWA:034US/SLH	6493

7590

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/025,187	SHEFFIELD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 42-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to the action received 11/1/04.

Claims 42-53 are pending and will be examined as they read on the elected species- SEQ ID NO:1.

#### ***Claim Rejections - 35 USC § 103***

Claims 42-53 are/stand rejected under 35 U.S.C. 103(a) for the reasons of record which are restated below.

The claimed invention is drawn to a method of diagnosing Bardet-Biedl Syndrome (BBS) comprising identifying a mutation in a NGVN nucleic acid.

Landegren teaches an assay for determining the nucleic acid sequence in a region of a nucleic acid test substance having a known normal sequence and a known possible mutation at at least one target nucleotide position. Landegren discloses the assay is particularly useful for analyzing nucleic acids for the diagnosis of infectious and genetic disease. See, e.g., for example, abstract, column 2, column 5, and column 20, claim 1. Landegren does not teach diagnosing Bardet-Biedl Syndrome.

Hoang teaches chromosomal mapping of the KIFC3 gene within the critical region for Bardet-Biedl syndrome (BBS2), since KIFC3 maps within the BBS2 region and the expression pattern correlates well with the clinical symptoms of Bardet-Biedl Syndrome, KIFC3 should be

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considered a good candidate for families linked to BBS2. See, e.g., for example, abstract, page 219, page 222.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the assay for determining the nucleic acid sequence in a region of a nucleic acid test substance having a known normal sequence and a known possible mutation at at least one target nucleotide position of Landegren with the beneficial teachings of Hoang, because Landgren discloses the assay is particularly useful for analyzing nucleic acids for the diagnosis of infectious and genetic disease.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the present claims are drawn to diagnosing BBS by detecting mutations in a NGVN polypeptide and that the cited references do not mention this molecule, thus making the rejection improper in failing to teach a specific limitation of the claim. However, the examiner contends that the claim recites a polypeptide or nucleic acid.

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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1/7/05

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER